AUG 2 3 2005

510(k) Summary
VitalCare Group, Inc.
8935 NW 27th Street
Miami, FL 33172
Tel 305-620-4007
Fax 305-620-9989
Contact: Ramzi Abulhaj, President
Date: August 15, 2005

I. Device: "3 In 1" I V Administration Set

Common Name:	I. V. Administration Set
Classification Name:	Set, Administration, Intravascular
Panel:	General Hospital and Personal Use
Product Code:	FPA
Device Classification:	II

II. DEVICE DESCRIPTION

The 3 in 1 IV Administration Set is a single use, sterile, device sterilized with Ethylene Oxide gas. The 3 in 1 set is used to administer fluids from an IV container or syringe to a patient's vascular system through a needle or catheter. A choice can be easily made between 10, 15, or 60, drops/cc volume without breaking the line. This feature allows the healthcare provider the flexibility to treat the patient condition by turning the selector. The device may include a flow regulator, a drip chamber, backflow valve, fluid delivery tubing, connectors between parts of the set, needleless injection site, Y port, extension set, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container. VitalCare Group Inc. will offer standard sets and custom sets to meet customer requirements and specifications.

III. INTENDED USE OF THE DEVICE

The 3 in 1 IV Administration Set is used to administer fluids front a container to a patients vascular system through a needle or catheter inserted into the vein. The device may include the tubing, a flow regulator, drip chamber, backflow valve, fluid delivery tubing, connectors between parts of the set and a hollow spike to connect the tubing to an IV bag or medication bag.

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Comparison Table

Feature	Detail	Predicate K925465
Intended Use	The VitalCare 3 in 1 IV Administration Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The device may include the tubing, a flow regulator, drip chamber, Y port, needleless injection port, backflow valve, fluid delivery tubing, connectors between parts of the set and a hollow spike to connect the tubing to an IV bag or medication bag.	Identical
Components	Spike, ABS, Polylac PA-747 Spike Cover, PE Luer Locks, Male and Female, ABS, Polylac PA-747 Luer Protective Covers, Polypropylene R701G PVC Tubing, Medical Grade DEHP free, 2228GBF-65S Clear Y Port/Split Septum, ABS, Polylac PA-747 Needleless Y Port, ABS, Polylac PA-747 Extension Tube, Medical Grade DEHP free PVC/ABS 3 in 1 Flow Regulator, ABS, Polylac PA-747 Back Flow Valve, ABS, Polylac PA-747 Roller Clamp, ABS, Polylac PA-747 Tube Clamp, ABS, Polylac PA-747 Pouch, Polypropylene R701G Kraft triple wall Corrugated fiberboard	Similar components and materials
Performance Tests	Biocompatibility Bench Testing Sterilization/Residuals	Similar
Labeling	Reorder Number Size Quantity Lot Number Sterile Bar Code DEHP Free Latex Free Single Use Only Pouch and Shipping case Manufacturer Address	Similar
Packaging	50 pouches per case	Similar
Sterilization	Sterile (EO)	Sterile (EO)

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IV Performance Data

Pull testing, pressure testing, joint strength testing, and drop testing has been performed.

V. Conclusion

The VitalCare "3 in 1" IV Administration Set is substantially equivalent to the above products by having the identical indication for use and similar materials used for construction.

The materials used to manufacture the VitalCare IV Administration Set are used in legally marketed devices under comparable conditions.

Comparison of the predicate device to the VitalCare IV Administration Set for technological differences showed no significant difference.

VI. Description of the Marketed Equivalent Device:

Common Name:	IV Administration Set
Classification Name:	Set, Administration, Intravascular
Product Code:	FPA
Applicant:	Biomedix Inc. 23 South Main Street P. O. Box 231 Spencer, IN 47460
Equivalent Device	K925465, IV Set

VII Intended Use of the Marketed Equivalent Device:

The Selec-3 is an adjustable 3 in 1 volume IV Set is used to administer fluids from a container to a patients vascular system through a needle or catheter inserted into the vein. The device may include the tubing, a flow regulator, drip chamber, an infusion line filter, backflow valve an IV set stopcock, fluid delivery tubing, connectors between parts of the set and a hollow spike to connect the tubing to an IV bag.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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VitalCare Group, Incorporated
C/O Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K050906
Trade/Device Name: VitalCare I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 7, 2005
Received: July 7, 2005

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

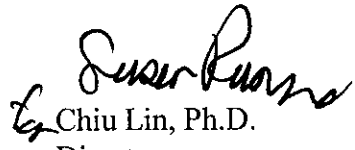
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):_____

Device Name:_VitalCare I. V. Administration Set

Indications For Use: The Intravascular Administration Set is a single use, sterile device that provides access for the administration of fluids from a container to the patients vascular system through the administration set's needle or catheter, which is inserted into a vein.

Prescription Use ___√____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K995106